

REMARKS

The Examiner has required restriction of the claimed invention, and listed the following group classifications:

Group Claims	Description
I 1-4, 9-11, 13-16, 19 and 20	heterologous antigen + human hepatitis B virus (HBV) core
II 5	heterologous antigen + HBV core + immune enhancer
III 6-8	heterologous antigen + HBV core
IV 12	heterologous antigen + HBV core
V 17	nucleic acid
VI 18	expression vector
VII 21-24	method for inducing an immune response
VIII 25-30	method for manufacturing an immunogenic composition

Applicants hereby elect to prosecute the method claims of Group VIII, without traverse of the restriction between Claims 25-30 and Claims 1-24. However, Applicants believe that the Examiner's restriction of the composition claims of Group I-VI is improper. Nonetheless, Applicants have canceled Claims 1-24, amended Claims 25-27, and entered new Claims 31-55, in order to further the prosecution of the present application and Applicants' business interests, without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s).

Support for the amendments and the new claims can be found in the application as filed. In particular, support for amended Claims 25 and 26 is found in the Summary, which discloses that the present invention provides methods comprising "altering at least one of the heterologous antigen and the hepatitis virus core antigen" (*See, e.g.,* Specification, paragraph [0011]). Support for amended Claim 27, and new Claims 31-49 and 55, is found for instance in original Claims 27 and 30, as well as Example 15 and Table 18, which describe the effects of insert pI and linker addition on particle assembly. Further support for new Claims 36-45 and 55 is found for instance in Example 8, which teaches that insert position, C-terminal sequence, and epitope sequence are three variables that must be considered in designing hybrid hepatitis virus particles. Additional support for Claims 36-45 can be found in Tables 1, 3, 4, 9, 10, and 12-14, as well as

in original Claims 25-30. Moreover, support for Claims 50-54 is found in the definition section of the application as filed, which teaches that hepatitis B virus is a orthohepadnavirus and that viruses similar to "HBV also infect animals (e.g., woodchuck, ground squirrel, duck), and are encompassed by some embodiments of the present invention" (See, Specification, paragraph [0120]). Accordingly, the amendments and new claims do not introduce new matter and do not narrow the scope of any of the claims within the meaning of *Festo*.¹

In addition, Applicants have amended the Specification to correct a clerical error. In particular, Applicants have amended the Summary to recite "the amino acid sequence set forth in SEQ ID NO:58, the amino acid sequence comprising a loop region and further comprising from 1 to 100 amino acids at the carboxy end of residue V¹⁴⁹". Support for this amendment is provided by Figure 42 panel C depicting the amino acid sequence of SEQ ID NO:58 having a valine rather than an isoleucine at position 149.

Conclusion

Applicants hereby elect to prosecute the method claims of **Group VIII** without traverse of the restriction between Claims 25-30 and Claims 1-25. Applicants request consideration of the references listed on the Information Disclosure Statements submitted to the Office on October 31, 2003, January 26, 2004 and September 7, 2004, before mailing of a first substantive Office Action. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect.

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By: _____



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¹ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002).